WO

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Doris Jones and Alfred Jones, Sr., a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00782-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs have received implants of Bard IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious injury or death.

The case brought by Doris and Alfred Jones has been selected as one of several bellwether cases and is set for trial in May 2018. Defendants have filed a motion for partial summary judgment. Doc. 7351. The motion is fully briefed, and the parties agree

that oral argument is not necessary. For reasons set forth below, the Court will grant the motion in part and deny it in part.[1]

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a small metal device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. They are spider-like devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with elastic hooks that attach to the IVC wall and curved arms that serve to catch or break up blood clots. Each of these filters is a variation of its predecessor.

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn physicians and patients about these higher risks. Plaintiffs assert a host of state law claims and seek both compensatory and punitive damages. Defendants dispute Plaintiffs' allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

II. Plaintiffs Doris and Alfred Jones.

In August 2010, before gastrointestinal surgery, Doris Jones was implanted with an Eclipse filter due to recurrent deep vein thrombosis. Dr. Anthony Avino implanted the filter without incident. In April 2015, Mrs. Jones went to the emergency room with complaints of lightheadedness and arm pain. A chest scan revealed a fractured filter limb

---

[1] The motion redacts certain information concerning Mrs. Jones's personal medical history. Doc. 7531. Defendants have filed an unredacted version of that brief under seal. Doc. 7354. The Court will cite to the redacted motion in addressing the summary judgment arguments.

that had embolized in the right pulmonary artery. The filter was removed but the fractured limb remains in place.

Mrs. Jones and her husband assert various claims under Georgia law, some of which have been withdrawn. The following claims remain: failure to warn (Counts II and VII), design defects (Counts III and IV), misrepresentation (Counts VIII and XII), negligence per se (Count IX), fraudulent concealment (Count XIII), consumer fraud and unfair trade practices (Count XIV), loss of consortium (Count XV), and punitive damages. *See* Doc. 364 (master complaint); Doc. 1, CV-16-00782-PHX-DGC (short-form complaint).[2]

Defendants seek summary judgment on the failure to warn, misrepresentation, negligence per se, consumer fraud and unfair trade practices, and punitive damages claims. Doc. 7351 at 3. Plaintiffs concede that summary judgment is proper on the consumer fraud and unfair trade practices claim. Doc. 7943 at 2 n.1. The Court will grant summary judgment on that claim and the misrepresentation and negligence per se claims. The Court will deny summary judgment on the failure to warn and punitive damages claims.[3]

III. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v.*

---

[2] The master complaint is the operative pleading for most of the cases in this MDL. It was created for the sake of convenience and serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert generally. Plaintiff-specific allegations are contained in individual short-form complaints or certain complaints served on Bard before the filing of the master complaint. *See* Doc. 249 at 6. Plaintiffs also provide Bard with profile forms and fact sheets that describe their individual conditions and claims. *See* Doc. 365.

[3] Defendants do not seek summary judgment on the claims for design defect (Counts III and IV), fraudulent concealment (Count XIII), and loss of consortium (Count XV). Plaintiffs withdrew the followings claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), negligent failure to recall or retrofit (Count VI), and breach of warranty (Counts X and XI). *See* Doc. 7351 at 2. Plaintiffs do not assert claims for wrongful death or survival (Counts XVI and XVII).

Catrett, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence must be viewed in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and all justifiable inferences are drawn in that party's favor because "[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions," *Anderson*, 477 U.S. at 255.

IV. Failure to Warn (Counts II and VII).

Georgia law applies in this case because the alleged injuries occurred in Georgia and Plaintiffs lived there when their complaint was filed. Doc. 7351 at 5; Doc. 1 ¶¶ 4-6, CV-16-00782-PHX-DGC. To establish a failure to warn claim under Georgia law, "the plaintiff must show that the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999). "[A] manufacturer has a duty to warn of nonobvious foreseeable dangers from the normal use of its product." *Thornton v. E.I. Du Pont de Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994). The duty to warn arises "whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). The duty may be breached in two ways: "(1) failing to adequately communicate the warning to the ultimate user or (2) failing to provide an adequate warning of the product's potential risks." *Thornton*, 22 F.3d at 289.

In cases involving medical devices, Georgia applies the "learned intermediary" doctrine. Under this doctrine, the manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor,

who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer's warnings to the physician, however, "must be adequate or reasonable under the circumstances of the case." *Id.*

In this case, Plaintiffs allege that Bard failed to adequately warn physicians about the known defects and higher complication rates associated with Bard filters. Doc. 364 ¶¶ 174-78, 211-16. Plaintiffs claim that this failure constitutes a breach of Bard's duty to warn and proximately caused their injuries. *Id.* ¶¶ 177-81, 215-17. Plaintiffs assert strict liability and negligence claims for the alleged failure to warn. *Id.* ¶¶ 171-81, 202-09; *see* Doc. 1 at 3, CV-16-00782-PHX-DGC.

Defendants contend that proximate cause is lacking because Dr. Avino did not read the Eclipse filter's instructions for use ("IFU") and had actual knowledge of the risk of fracture. Doc. 7351 at 6-7. Defendants further contend that the warnings provided with the Eclipse filter were adequate because they included the complication experienced by Mrs. Jones. *Id.* at 8-11. The Court will address each argument.

A. Causation.

1. Failure to Read the Eclipse IFU.

Defendants rely on *Wilson Foods Corp. v. Turner*, 460 S.E.2d 532, 534 (Ga. Ct. App. 1995), for the proposition that "failure to read product instructions . . . will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the products' potential risk." Doc. 7351 at 6. Defendants contend that Dr. Avino did not read the Eclipse IFU before implanting the device in Mrs. Jones, and Plaintiffs therefore cannot show that any warning inadequacy proximately caused their injuries. *Id.*

But the duty to warn is breached not only by having a deficient warning, but also by "failing to adequately communicate the warning to the ultimate user." *Thornton*, 22 F.3d at 289. Indeed, *Wilson* makes clear that failure to read instructions "'does not bar recovery where the plaintiff is challenging the adequacy of the efforts of the manufacturer or seller to communicate the dangers of the product to the buyer or user.'"

460 S.E.2d at 534 (quoting *Thornton*, 22 F.3d at 290). Plaintiffs bring such a challenge in this case.

Plaintiffs claim that the instructions contained in the IFU were inadequate, and that Bard otherwise failed to communicate sufficient warnings to physicians. Specifically, Plaintiffs allege that Bard breached its duty to warn by not "providing instructions for safe use" or "communicating the information and dangers" about Bard filters to physicians. Doc. 364 ¶¶ 181, 216. Plaintiffs note that medical device warnings are provided in various ways, including "dear doctor" letters, product pamphlets, and statements by the company sales representatives. Doc. 7943 at 14 (citing *Allen v. Belinfante*, 458 S.E.2d 867, 869 (Ga. Ct. App. 1995) (assessing doctor's awareness of "dear doctor" letters and other sources of information about potential risks in determining liability for failure to warn claim)); *see PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011) (noting that manufacturers provide warnings through dear doctor letters).

Given Plaintiffs' claim that Bard breached its duty to warn by failing to adequately communicate warnings to physicians through means other than IFUs, the fact that Dr. Avino may not have read the Eclipse IFU is not dispositive on causation. *See Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1247 (N.D. Ga. 2002) ("A plaintiff's failure to read a warning will not . . . bar recovery as to the first prong of the test: namely, where the plaintiff is challenging the *adequacy* of the defendant's efforts to communicate the dangers of the product to the user[.]" (citing *Wilson*, 460 S.E.2d at 534)); *In re Stand 'n Seal Prods. Liab. Litig.*, No. 1:07MD1804-TWT, 2009 WL 2145911, at *6 (N.D. Ga. July 15, 2009) (denying summary judgment where the plaintiffs did not read the warning label but claimed that the manufacturer's efforts to communicate the dangers were inadequate (citing *Wilson*)); *Mizell v. Pilgrim's Pride Corp.*, No. CV 509-064, 2012 WL 130056600, at *5 (S.D. Ga. Mar. 14, 2012) (finding the failure to read a warning not dispositive where the plaintiff challenged the manufacturer's communication of the warning (citing *Wilson*)); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2007 WL 4117201, at *2 (M.D. Fla. Nov. 6, 2007) (denying summary judgment

where the plaintiffs alleged that the manufacture failed to communicate drug risks in dear doctor letters and promotional materials used by sales representatives); *see also Flowers v. Eli Lilly & Co.*, No. 3:14-cv-0094-LHR-VPC, 2015 WL 12622058, at *3 (D. Nev. July 10, 2015) (manufacturer met its duty to communicate potential risks by sending dear doctor letters to physicians).[4]

2. Knowledge of the Risk.

Defendants note that the causal link is generally broken where the treating physician has actual knowledge of the risk. Doc. 7351 at 7. Defendants contend that proximate causation is lacking in this case because Dr. Avino was aware of IVC filter complications – including fracture – before implanting the Eclipse filter in Mrs. Jones. *Id.* Defendants further contend that Bard cannot be liable for failure to warn because IVC filter complications are well known by the medical community. *Id.* at 9.

Plaintiffs concede that Bard warned Dr. Avino and other physicians about filter complications generally, but contend that the warnings were inadequate because Bard did not disclose that the risk of complications for the Eclipse filter was *higher* than those of other IVC filters, including Bard's own Simon Nitinol Filter ("SNF"). Doc. 7943 at 6-7, 10-11. Plaintiffs present evidence that the Eclipse and its predecessor devices, the Recovery and G2 line of filters, involved substantially greater risks of fracture than other IVC filters. Doc. 7943 at 4. Plaintiffs claim that Dr. Avino was not aware of the higher risks, and that he would have wanted to know this information when deciding whether to implant the Eclipse filter in Mrs. Jones. *Id.* Dr. Avino testified that his initial understanding was that the fracture rates for Bard filters were very low, and he learned

---

[4] The parties dispute whether Dr. Avino actually read the Eclipse IFU. Dr. Avino testified that he sometimes reads IFUs, but does not read them on every package where the product is the same, and that he does not specifically recall if he read the Eclipse IFU. Doc. 7357-3 at 5. Plaintiffs contend that Dr. Avino was aware of the warnings in the Eclipse IFU because he read those very warnings for Bard's G2 line of filters. Doc. 7943 at 13. The Court finds that there is a genuine factual dispute on this issue that is best resolved by the jury. *See In re Stand 'n Seal*, 2009 WL2145911, at *6 (finding triable issue where the plaintiff could not remember whether he read the warnings and noting that "[i]ssues of causation are for the jury to resolve and should not be determined by a trial court as a matter of law except in plain and undisputed cases").

only during the past several years that the rates were higher. Doc. 7974 at 42-43. He further stated that the time period in which he treated Mrs. Jones "predates the peak of his concern and the release of the warnings about the complications of filters." *Id.* at 33-34. He made clear that if Bard knew about higher complication rates associated with its filters before Mrs. Jones's surgery, he would have wanted to know that information. *Id.* at 34, 45-46.

Construed in Plaintiffs' favor, Dr. Avino's testimony is sufficient evidence of causation at the summary judgment stage. A jury reasonably could infer that he would not have implanted the Eclipse filter in Mrs. Jones had he been warned about higher fracture rates. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. CV 2:10-cv-01224, 2013 WL 2431975, at *7 (S.D. W. Va. June 4, 2013) (denying summary judgment where the doctor never explicitly stated that he would not have used Bard's product had he been provided additional warnings, but explained that the information would have been "helpful" and "nice to have"); *Cason v. C. R. Bard, Inc.*, No. 1:12-CV-1288-HMS, 2015 WL 9913809, at *6 (N.D. Ga. Feb. 9, 2015) (denying summary judgment where the doctor stated that "he would have wanted to know if the G2 Filter had a significantly higher risk of complications than other IVC filters"). Georgia law is clear that summary judgment is warranted on the issue of causation only where the physician testifies unequivocally that he would have made the same decision despite the proposed warning. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (doctor provided "explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [the anti-depressant]"); *Porter v. Eli Lilly & Co.*, No. 1:06-CV-1297-JOF, 2008 WL 544739, at *13 (N.D. Ga. Feb. 25, 2008) (doctor "unequivocally testified that even if he had read the warning that [plaintiff] asserts should have been given, he still would have prescribed [the anti-depressant] to the decedent"). Defendants cite no such testimony from Dr. Avino.[5]

[5] Defendants assert in their reply that Plaintiffs did not ask Dr. Avino during his

Defendants' reliance on *In re Wright Medical Technology Inc.*, 127 F. Supp. 3d 1306 (N.D. Ga. 2015), is misplaced. Doc. 7351 at 7. The undisputed evidence in that case showed that the physician educated himself about product risks by reviewing the medical literature, had never read package insert warnings for any device he implanted, and did not have access to the insert prior to the plaintiff's surgery because it was in a sterile package. 127 F. Supp. 3d at 1359-60. Moreover, the failure to warn claim was governed by Utah law, not the law of Georgia. *See id.* at 1358.

Defendants' reliance on *Wheat* and *Ellis* fares no better. Doc. 7351 at 7-9. Each treating physician in *Wheat* unequivocally testified that "he was aware of the risks associated with spinal implant surgery, that such risks were well known in the medical community, and that he would have taken the same course of action in spite of the information [the plaintiffs] contend[ed] should have been provided." 46 F. Supp. at 1363. *Ellis* held that a medical device manufacturer has no duty to warn anyone other than the learned intermediary, and granted summary judgment because it was undisputed that this duty had been met. 311 F.3d at 1281-83 ("[W]e conclude that Georgia's learned intermediary rule controls this case, [and] that the defendants adequately warned the doctors . . . of the damages of third-party [pain pump] activation[.]").[6]

B. Adequacy of the Warnings.

The Eclipse IFU included the following warnings:

> Filter fracture is a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with

---

deposition whether a different warning would have mattered. Doc. 8391 at 10. But apparently neither did Defendants. Absent unequivocal testimony in this regard, summary judgment is not warranted. *See Watkins v. Eli Lilly & Co.*, No. 1:08-CV-1665, 2010 WL 11493785, at *9 (N.D. Ga. Mar. 31, 2010) (denying summary judgment where the defendant failed to "nail[] this matter down" through deposition testimony).

[6] Defendants assert in their reply that Plaintiffs have presented no evidence that the Eclipse filter fractured at a significant enough rate to render Bard's warnings about fracture inadequate. Doc. 8391 at 9. Plaintiffs present evidence of significantly higher fracture rates for the G2 filter, claim that the Eclipse is essentially the same as the G2, and dispute whether electropolishing of the Eclipse was effective in reducing fracture rates experienced by the G2. *Id.* at 4 n.3, 16. Given this evidence, the fracture rate for Eclipse filters is an issue for the jury.

> vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
>
> . . . .
>
> [T]he above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Doc. 7352-1. Defendants contend that these warnings were adequate as a matter of law because they included a risk of fracture – the very complication experienced by Mrs. Jones. Doc. 7351 at 8-9. Plaintiffs argue that the warnings were inadequate because they did not include risk rates or disclose that the risks associated with the Eclipse filter were higher than those for the SNF and other IVC filters. Doc. 7943 at 10. Anticipating this argument, Defendants counter that Georgia law imposes no duty on a manufacturer to provide comparative risk rates for its product and those of competitors. Doc. 7351 at 9-10.

The Court addressed this issue in ruling on Defendants' summary judgment motion in the Booker case. Agreeing with the decisions in *Cason* and *Cisson*, which applied Georgia law, the Court found that whether Bard's warnings were adequate is a question of breach, not duty. Doc. 8874 at 6-7 (citing *Cason*, 2015 WL 9913809, at *4-5; *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *7 (S.D. W. Va. Oct. 18, 2003)). The Court reaches the same conclusion in this case.

The Court further finds that the alleged failure to warn about the rate of complications raises a jury question over the adequacy of Bard's warnings. "The general rule in Georgia is that the adequacy of the warning is an issue for the jury [unless] . . . the facts support only one conclusion, that is, the warning and its communication were adequate." *Thornton*, 22 F.3d at 289 (citations omitted). The evidence presented in this case, when construed in the light most favorable to Plaintiffs, *see Matsushita*, 475 U.S. at 587, supports a finding that Bard's warnings for the Eclipse filter were not "adequate

or reasonable under the circumstances of the case." *McCombs*, 587 S.E.2d at 595. The "question that must be answered by the fact finder is whether the warning given was sufficient or was inadequate because it did not 'provide a complete disclosure of the existence and extent of the risk involved.'" *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1220 (11th Cir. 1999) (quoting *Thornton*, 22 F.3d at 289). In short, whether the warnings should have included comparative risk rates will be for the jury to decide. *See Cason*, 2015 WL 9913809, at *5 ("Given . . . that defendants did not warn Mrs. Cason's doctor about any increased risk associated with the G2 Filter, a reasonable fact finder could conclude that the IFU did not contain an adequate warning[.]"); *Cisson*, 2013 WL 5700513, at *7 (failure to warn about "the rate or severity of potential injury creates a jury question over the adequacy of warnings"); *Watkins*, 190 F.3d at 1219-20 (denying summary judgment on failure to warn claim where Ford's internal documents showed that the Bronco II had a rollover fatality rate more than three times that of other SUVs and the vehicle was rated last in government stability tests); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010) (finding a triable issue on adequacy of warning where the product had a greater propensity to cause complications and was associated with more severe complications than other products).

Defendants contend that Georgia law does not require a manufacturer to provide comparative rates of complications for its products. Doc. 7351 at 9-10 (citing *Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 693 S.E.2d 888, 892 (Ga. Ct. App. 2010); *Hoffman v. AC & S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). But as previously explained (Doc. 8874 at 9), the cases cited by Defendants concern very different questions: whether a manufacturer can be liable for injuries caused by modifications another party made to its product, *Dixie Grp.*, 693 S.E.2d at 892, and whether a plaintiff must show that it was the defendant's asbestos product – as opposed to asbestos products generally – that caused her mesothelioma, *Hoffman*, 548 S.E.2d at 382. "Nothing in these cases suggests that a manufacturer's warning is adequate even if it fails to warn that the product is

significantly more dangerous than other similar products on the market." *Cason*, 2015 WL 9913809, at *5.

Defendants state in their reply that including warnings about comparative risk rates "is almost certainly precluded by FDA regulations," but they cite no specific regulation in support of this assertion. Doc. 8391 at 6. Defendants' reliance on cases involving prescription drugs is misplaced because those cases concern a specific FDA regulation not applicable to medical devices such as the Eclipse filter. *See* 21 C.F.R. § 201.57(c)(7) ("The requirements in this section apply only to prescription drug products[.]").

Defendants further state that providing comparative warnings would be impossible because the data for defining actual rates is inherently unreliable and ever-changing. Doc. 8391 at 6-7. The question, however, is not whether Defendants were able to provide completely accurate and up-to-date failure rate comparisons, but whether, prior to Mrs. Jones's surgery, "they had sufficient information such that they knew or should have known that use of the [Eclipse filter] involved a significantly increased risk of [fracture] as compared to other IVC filters." *Cason*, 2015 WL 9913809, at *6. As explained above, a jury reasonably could conclude that Defendants had such information and therefore had a duty to warn Dr. Avino of the increased risk.

Finally, Defendants contend that summary judgment is warranted because Plaintiffs have identified no alternative warning. Doc. 8391 at 8-9 (citing *Nolley v. Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007 WL 5369405, at *6 (N.D. Ga. Dec. 6, 2007)). To the contrary, Plaintiffs make clear Bard should have disclosed to implanting physicians such as Dr. Avino that Bard filters (including the Eclipse) fractured at rates significantly higher than the SNF and competitor filters. Doc. 7943 at 2, 7, 10. The jurors in this case, unlike in *Nolley*, will be presented with proposed warnings and will have a means by which to determine whether the actual warnings were adequate.

In summary, there are triable issues as to whether Bard's warnings in this case

were adequate and whether Bard sufficiently communicated the warnings to Dr. Avino. The Court will deny summary judgment on Plaintiffs' failure to warn claims (Counts II and VII).

V. Misrepresentation (Counts VIII and XII).

Defendants contend that the misrepresentation claims fail for the same reasons the failure to warn claims fail, namely, that Bard provided adequate warnings and the alleged failure to warn could not be the proximate cause of Plaintiffs' injuries. Doc. 7351 at 6. For reasons explained above, the failure to warn claims survive summary judgment.

Defendants also note, however, that Georgia does not recognize a claim for misrepresentation apart from a failure to warn claim in products liability cases. *Id.* at 6 n.2.[7] Defendants rely on two district court cases: *Brazil v. Janssen Research & Development, LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016), and *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008). In *Swicegood*, the plaintiff brought a products liability action after she allegedly suffered an adverse reaction to a generic prescription drug. 543 F. Supp. 2d at 1353. The plaintiff alleged, among other things, that the defendants knew that long-term use of the drug posed a greater risk of causing the adverse reaction than they disclosed to the FDA or the public. *Id.* The plaintiff asserted several claims under Georgia law, including strict products liability, failure to warn, and misrepresentation. *Id.* at 1353-57. The court concluded that "misrepresentation claims against a manufacturer properly collapse into the failure to warn claims." *Id.* at 1357. Absent clear Georgia precedent, the court declined "to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims." *Id.*

The court in *Brazil* reached a similar conclusion. The court dismissed the plaintiff's

---

[7] Defendants made the same argument in seeking summary judgment on the misrepresentation claims in the Booker case (Doc. 7460 at 7-8 n.3), but withdrew this position at oral argument in Booker for reasons they did not explain (*see* Doc. 8874 at 14 n.5).

misrepresentation claim, noting that *Swicegood* had "determined that there [are] no misrepresentation claims for products liability distinct from failure to warn claims." 249 F. Supp. 3d at 1340; *see Gaddy v. Terex Corp.*, 1:14-cv-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. May 5, 2017) (same).

The Court finds these rulings by Georgia-based federal judges, applying Georgia law, to be persuasive. *See also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 856 F. Supp. 2d 904, 910 (E.D. Ky. 2012) (citing *Swicegood* and noting that "courts in many states have expressly rejected the argument that misrepresentation claims are distinct from product liability or failure-to-warn claims" (citations omitted)). The Court will grant summary judgment on the misrepresentation claims (Counts VII and XII).

Plaintiffs note that *Potts v. UAP-GA AG CHEM, Inc.*, 567 S.E.2d 316, 318 (Ga. Ct. App. 2002), contemplated that a misrepresentation claim could be distinct from a failure to warn claim in a products liability suit. But the misrepresentation claim in *Potts* was truly distinct. It was asserted against the decedent's former employer for allegedly misrepresenting to a physician that the decedent was not exposed to the chemicals at issue. 567 S.E.2d at 319-20. Unlike the misrepresentation claims asserted in this case, the claim in *Potts* was distinct from the strict liability and failure to warn claims asserted against the manufacturer. *Id.* ("Here the misrepresentation was to LeBlanc's physician, on whom LeBlanc was relying for treatment. Through the misrepresentation, [the employer] induced the physician to discount the possibility of chemical poisoning and to change LeBlanc's treatment, on which treatment LeBlanc was relying for his physical recovery.").[8]

VI. Negligence Per Se (Count IX).

"In Georgia, 'the violation of a statute, ordinance or mandatory regulation that

[8] Defendants assert in their reply that even if Georgia recognized separate products liability misrepresentation claims, Plaintiffs offer no evidence of the required elements, such as scienter and justifiable reliance. Doc. 8391 at 12. The Court will not grant summary judgment based on an argument raised for the first time in a reply brief. *See Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007).

imposes a legal duty for the protection of others constitutes negligence per se.'" *Ashton Park Trace Apartments, LLC v. W. Oilfields Supply Co.*, No. 14-CV-4056-MHC, 2015 WL 12469074, at *6 (N.D. Ga. July 16, 2015) (citation omitted). This theory of liability is codified in a Georgia statute: "When the law requires a person to perform an act for the benefit of another or to refrain from doing an act which may injure another, although no cause of action is given in express terms, the injured party may recover for the breach of such legal duty if he suffers damage thereby." Ga. Code Ann. § 51-1-6.

Plaintiffs allege that Defendants are liable for negligence per se because they violated various provisions of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and related regulations, by misbranding Bard filters, making false and misleading statements about the filters, failing to notify the FDA when the filters were no longer safe and effective, failing to recall the devices, and not maintaining accurate adverse event reports. Doc. 364 ¶ 231.[9] This claim is impliedly preempted under 21 U.S.C. § 337(a), Defendants argue, because no private right of action exists under the FDCA and all proceedings to enforce or restrain violations of the statute must be brought by the FDA. Doc. 7351 at 11-12. The Court agrees with Defendants.[10]

"The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Indeed, § 337(a) expressly provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Leonard v.*

---

[9] Specifically, Plaintiffs allege violations of 21 U.S.C. §§ 321, 331, 352, and 21 C.F.R. §§ 1.21, 801, 803, 807, 820. Doc. 364 ¶ 231(a)-(j).

[10] The Court reached the same conclusion in the Booker case. *See* Doc. 8874 at 14-18.

Medtronic, Inc., No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted).

Plaintiffs assert no violation of a Georgia ordinance, regulation, or statute in support of their negligence per se claim. Thus, "as in *Buckman*, [Plaintiffs'] negligence per se claim (or, more appropriately characterized, [their] negligence claim based solely on violations of the FDA-Imposed Requirements or other FDA regulations) is impliedly preempted by the FDCA." *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016); *see Buckman*, 531 U.S. at 353 (state law claim that a defendant violated the FDCA by making false statements to the FDA impliedly preempted by § 337(a) because the claim "exist[ed] solely by virtue" of the FDCA); *Leonard*, 2011 WL 3652311, at *8 (finding negligence per se claim preempted by § 337(a) where it "would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law").

Plaintiffs assert that *Leonard* is inapposite because, unlike Bard IVC filters, the medical device at issue in *Leonard* had been approved by the FDA through the rigorous premarket approval process. Doc. 7943 at 18. But this was not the basis for *Leonard*'s implied preemption finding. *Leonard* found implied preemption because "all proceedings to enforce or restrain violations of the FDCA 'shall be by and in the name of the United States.'" 2011 WL 3652311, at *7 (quoting § 337(a)). Moreover, preemption under § 337(a) is not limited to devices approved through the premarket approval process. The device at issue in *Buckman* – like the Eclipse filter in this case – was cleared for market under 510(k) review. 531 U.S. at 346-47.

Plaintiffs note that Georgia common law and § 51-1-6 recognize that laws which do not create a private right of action may nonetheless support a claim for damages. Doc. 7943 at 18-19 (citing *Amick v. BM & KM, Inc.*, 275 F. Supp. 2d 1378, 1282-83 (N.D. Ga. 2003) (finding that "the defendants breached the legal duties imposed by [Georgia code] sections 30-4-2 and 43-21-3 when they prohibited Amick and his service dog from staying at their hotel")). While it is true that courts generally have allowed a

negligence per se claim based on violation of a statute that does not expressly provide for a private right of action, "the plain language of § 337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails." *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014).

The Court will grant summary judgment on Plaintiffs' negligence per se claim because allowing the claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations. *See Leonard*, 2011 WL 3652311, at *7-8; *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (negligence per se claim preempted where it was based on allegations that the defendant violated the FDCA by selling a misbranded and adulterated product); *Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was "based entirely on violations of the FDCA and its implementing regulations"); *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding fraud on the FDA claim preempted where the plaintiff was not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely "*because* the conduct violates the FDCA.").

VII. Punitive Damages.

Under Georgia law, punitive damages may be awarded only where the defendant's actions "showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). Defendants contend that punitive damages are not warranted because there is no evidence Bard acted with the requisite state of mind, and Bard otherwise complied with all applicable FDA regulations in bringing its filters to market. Doc. 7351 at 12-13. "Compliance with federal regulations, however, is not sufficient to automatically preclude an award of punitive damages." *Cason*, 2015 WL 9913809, at *6. This is particularly true where, as in this case, the device at issue was cleared by the FDA under 510(k) review which focuses primarily on equivalence with other products, not safety. *Cisson*, 2013 WL 5700513, at *12.

Plaintiffs claim that Bard's actions show a conscious indifference to the dangerous consequences posed by the Eclipse and its predecessor filters. Doc. 7943 at 19-23. Plaintiffs argue that a jury reasonably could award punitive damages because there is evidence that Bard knew that its retrievable filters were less safe than the SNF and were failing at higher rates than competitor devices, and yet never identified the root cause of the failures, provided adequate warnings, or recalled or suspended sales of Bard filters. *Id.* at 20-23. The Court previously found that Plaintiffs have presented evidence that, if believed by a jury, would be sufficient to support a finding that Bard knew the G2 filter was failing at significantly higher rates than other IVC filters, but did nothing to correct the problem or to warn doctors of the increased risk. Doc. 8874 at 20. Plaintiffs claim that the Eclipse is just a rebranded G2 or G2X filter, citing an internal Bard document explaining that the filter's name was changed to "break with the baggage associated with the previous versions despite the fact that the new iteration was the same as G2X in every way but one." Doc. 7943 at 22 (citing Doc. 7950 ¶ 102, Ex. 99).[11]

Defendants counter that the design change made to the Eclipse – electropolishing – was intended to improve fracture resistance and precludes a finding that Bard did "nothing" to address the issue of fracture. Doc. 8391 at 15-16. But Plaintiffs claim that Bard consciously chose not employ other known safety features in the Eclipse such as penetration limiters and caudal anchors to reduce the risk of perforation, tilt, and migration. Doc. 7943 at 22. Plaintiffs' expert on the design of Bard filters opines that filter failure modes can work synergistically, and that fractures are more likely to occur when a filter tilts, migrates, or perforates the IVC wall. Docs. 7807-1 at 21, 7319-1 at 37-38. Plaintiffs contend that the Eclipse suffered from the same design defects and caused the same type of injuries as its predecessors, and that rather than recalling the product from the market, making substantive design changes to improve patient safety, or warning physicians about the dangers, Bard simply renamed the device and continued

[11] The only modification to the G2X from the G2 was the addition of a snare hook to improve retrievability. The filters otherwise are the same.

selling it. Doc. 7943 at 22. Plaintiffs claim that the Eclipse was used as a stop-gap device so that Bard could maintain market share and profits while it engaged in a complete redesign of the filter. *Id.* at 22, 24-25.

Defendants vigorously dispute this view of the evidence, and claim that Bard could not have brought its subsequent generation filters to market by the time Mrs. Jones received an Eclipse filter. But if a jury were to believe Plaintiffs' version of events, it reasonably could "conclude that Bard acted with an entire want of care such that Bard was consciously indifferent to the consequences of its actions." *Cisson*, 2013 WL 5700513, at *14.

Defendants contend that incidents involving the Recovery and G2 line of filters are irrelevant because Plaintiffs cannot show a "substantial similarity" between those devices and the Eclipse. Doc. 8574 at 14-16. "To show substantial similarity, the plaintiff must come forward with evidence that the other 'incidents share a common design, common defect, and common causation with the alleged design defect at issue.'" *Chrysler Grp., LLC v. Walden*, 792 S.E.2d 754, 740 (Ga. Ct. App. 2016) (quoting *Colp v. Ford Motor Co.*, 630 S.E.2d 886, 889 (Ga. 2006)). Plaintiffs have met this burden.

It is undisputed that the Recovery filter was the predicate device for the G2, and Plaintiffs have presented evidence that the two devices share common design defects that have caused similar complications. *See* Docs. 8874 at 21, 10258 at 2-3. Plaintiffs also have presented evidence that the Eclipse is the same as the G2 line of filters with only one modification (electropolishing). Doc. 7950 ¶¶ 96, 101-102. Although the Eclipse may not be identical to the Recovery and G2, Plaintiffs have shown a "substantial similarity" between the filters.

IT IS ORDERED:

1. The following claims are **dismissed** based on Plaintiffs' withdrawal of the claims before Defendants moved for summary judgment: manufacturing defect (Counts I and V), negligent failure to recall or retrofit (Count VI), and breach of warranty (Counts X and XI).

2. Defendants' motion for partial summary judgment (Doc. 7351) is **granted in part and denied in part**. The motion is granted with respect to Plaintiffs' claims for misrepresentation (Counts VIII and XII), negligence per se (Count IX), and consumer fraud and unfair trade practices (Count XIV). The motion is denied with respect to the claims for failure to warn (Counts II and VII) and punitive damages. These claims, along with the claims for design defect (Counts III and IV), fraudulent concealment (Count XIII), and loss of consortium (Count XV), remain for trial.

3. A final pretrial conference is set for **May 4, 2018 at 10:00 a.m.** Doc. 10324. The trial is set to begin on **May 15, 2018 at 9:00 a.m**. Doc. 8144.

Dated this 12th day of March, 2018.

David G. Campbell
United States District Judge